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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,511	01/23/2002	Matthew L. Parsons	71710-56440	9369

24536 7590 07/21/2003

GENZYME CORPORATION
LEGAL DEPARTMENT
15 PLEASANT ST CONNECTOR
FRAMINGHAM, MA 01701-9322

EXAMINER

LACYK, JOHN P

ART UNIT	PAPER NUMBER
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3736

12

DATE MAILED: 07/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,511

Applicant(s)

PARSONS ET AL. *ch*

Examiner

John P Lacyk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-68 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-56, 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. In claim 1, line 5, the use of "can be" is indefinite in that it is unclear whether the device is used as such or not. Similarly with claims 31-33, 36, 41, 56. Claim 2 fails to further limit the device and merely is directed to the intended use. In claim 18, the use of "may be" is indefinite as discussed above with respect to "can be". See also claim 60. Claims 31-33 should use "adapted to" language to avoid claiming a positive connection to the body. Further claims 31-33 fail to claim sufficient structure of the device to provide a complete device. Claim 32 defines a housing designed to "maximize the surface area" of the housing on the organ, but fails to provide sufficient structure that would allow or perform such a function. Claim 33 claims forming multiple, independent seals, but again fails to provide sufficient structure for the functional language. The claims must either set forth sufficient structural limitations to perform the functions or be in proper means plus function language. In claim 48, the holding mechanism is not a positively claimed element. In claims 52-56, the use of the phrase "ring-type" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "-type"), thereby rendering the scope of the claim(s) unascertainable. Further in claims 52-53, 55 the use of "capable of" is indefinite in that it is unclear whether the device is rotated or not.

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-6, 26-27, 31-32, 57-59, 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogojavlensky.

Bogojavlensky discloses a device having a housing having a top surface, sides and a flange that is adapted to adhere to the body to form a seal with the body.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 28-29, 42-47 are rejected under 35 U.S.C. 103(b) as being unpatentable over Bogojavlensky.

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Although Bogojavlensky does not specifically disclose the claimed angles or range of height, width, thickness, etc. of the device, the courts have shown that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (In re Aller et al, 105 USPQ 233) and therefore would have been obvious to one skilled in the art to discover the optimum size and/or dimensions of the device.

8. Claims 1, 3-4, 7, 10, 13, 26-27, 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Argenta et al.

Argenta et al discloses a device also having a housing having a top surface and sides that is adapted to adhere to the body to form a seal with the body. Argenta et al also teaches the use of a screen or reinforcing member.

9. Claims 8-9, 28-29, 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Argenta et al.

With regard to claims 28-29, 42-47, the claims are obvious for the same reasons as discussed above. With respect to claims 8-9, the courts have shown that it is an obvious expedient to modify the shape or form of a device (In re Dailey et al, 149 USPQ 47).

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10. Claims 1-19, 26-29, 31-33, 36-52, 57-68 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Spence et al.

11. Claims 1-7, 9-21, 26-29, 31-68 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by WO 01 17437.

12. Claims 1-7, 9-19, 26, 32-33, 36, 42-49, 52 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by EP 0919193.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P Lacyk whose telephone number is 703-308-2995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0858.



John P Lacyk
Primary Examiner
Art Unit 3736

J.P. Lacyk
June 23, 2003